DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 29, 2014

Mindways Software, Inc.
% Keenan Brown, Ph. D.
President/ Director of Research and Development
3001 S Lamar Blvd. Suite 302
AUSTIN, TX 78704

Re: K140342
Trade/Device Name: QCT Pro Asynchronous Calibration Module, CliniQCT
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Mineral Densitometer
Regulatory Class: II
Product Code: KGI
Dated: July 25, 2014
Received: July 31, 2014

Dear Dr. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140342

Device Name
QCT Pro Asynchronous Calibration Module, CliniQCT

Indications for Use *(Describe)*
The QCT Pro Asynchronous Calibration Module is intended to provide an alternative method for calibrating QCT data sets that are intended for analysis with QCT Pro Spine and Hip application modules. Installation of the QCT Pro Asynchronous Calibration Module does not alter the clinical indications for use of the QCT Pro Spine and Hip application modules. It does, however, provide an additional means of obtaining calibration data that does not require the simultaneous scanning of a patient with a CT calibration standard as is required when using the QCT Pro Spine and Hip application modules without the installation of the QCT Pro Asynchronous Calibration Module. Thus the QCT Pro Asynchronous Calibration Module facilitates: (1) retrospective assessment of bone density from CT scans acquired for other purposes, (2) assessment of bone density in conjunction with another medically appropriate procedure involving CT scans of the anatomical regions where estimating bone density is prescribed, and (3) assessment of bone density without a phantom as an independent measurement procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Tel: +1 512 912-0871 | Fax: +1 512 912-0872 | Email: info@qct.com

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Mindways Software, Inc.
3001 S Lamar Blvd, Suite 302
Austin, TX 78704, USA

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

Contact Information:	J. Keenan Brown, Ph.D. President and Director of Research and Development Mindways Software, Inc 3001 S Lamar Blvd, Ste 302 Austin, TX 78704 Phone:512-912-0871 Fax: 512-912-0871 Email: keenan@qct.com
Date:	July 24, 2014
Model Number:	CLINIQCT
Device/Trade Name:	QCT Pro Asynchronous Calibration Module, CliniQCT, QCT Pro CliniQCT
Common/Usual Name:	Bone Mineral Densitometer
Classification Name:	Bone Densitometer, 21 CFR 892.1170, Class II
Predicate Devices:	K894854: Mindways QCT Pro Bone Mineral Density Analysis Software Intended Use: Estimate bone mineral density within the spine.

K002113: Mindways QCT Pro CTXA Hip Bone Mineral Densitometer

Intended Use: Estimate bone mineral density at the proximal femur, T-Score calculation, aid in determining fracture risk.

K030330: QCT Pro CTXA Hip Extended Reference Data

Intended Use: Reference data for Z-Score calculation between ages 20 and 80.

Device Description

The QCT Pro Asynchronous Calibration Module is intended to extend the capabilities of QCT Pro bone mineral densitometer products (K894854, K002113, K030330) currently marketed by Mindways to the measurement of bone mineral content (BMC) and bone mineral density (BMD) from patient-specific CT images acquired without the simultaneous use of a CT calibration phantom. The QCT Pro bone mineral densitometer products distributed with or supplemented with the QCT Pro Asynchronous Calibration Module will be marketed under the name QCT Pro CliniQCT or more simply CliniQCT. Mineral calibration information with the asynchronous calibration method is obtained from phantom measurements acquired on the same CT scanner, operated in a substantially similar mode used to acquire a patient CT scan. The phantom measurements used for calibration purposes may be acquired before or after a patient CT scan to which they are to be applied. The asynchronous calibration mode facilitates: (1) retrospective assessment of bone density from CT scans acquired for other purposes, (2) assessment of bone density in conjunction with another medically appropriate procedure involving CT scans of the anatomical regions where estimating bone density is prescribed, and (3) assessment of bone density without a phantom as an independent measurement procedure. Retrospective bone density analysis provides bone density information without exposing a patient to additional ionizing radiation while combining CT studies results in an overall reduction in patient exposure to ionizing radiation relative to the expected radiation dose associated with performing the studies separately.

Intended Use

The QCT Pro Asynchronous Calibration Module is intended to provide an alternative method for calibrating QCT data sets that are intended for analysis with currently marketed QCT Pro Spine and Hip application modules. Installation of the QCT Pro Asynchronous Calibration Module does not alter the intended use of the QCT Pro Spine and Hip application modules, however, it facilitates an additional means of providing calibration data to QCT Pro that does not require the

simultaneous scanning of a patient with a CT calibration standard as is required when using the QCT Pro Spine and Hip application modules *without* the installation of the QCT Pro Asynchronous Calibration Module. Calibration data necessary for use with the QCT Pro Asynchronous Calibration Module is obtained from a standard QCT Pro QA phantom CT scan performed on the same CT scanner used to acquire patient CT images intended for analysis within QCT Pro operating in conjunction with the QCT Pro Asynchronous Calibration Module. The phantom CT scans used to obtain calibration data may be obtained either prior to or subsequent to patient CT scans.

Summary of Technological Characteristics and Comparison with Predicate Devices

QCT Pro when operated with the QCT Pro Asynchronous Calibration Module, collectively marketed as CliniQCT, provides estimates of bone mineral content (BMC) and bone mineral density (BMD) values similar to those obtained from the predicate QCT Pro bone densitometer devices (K894854, K002113, K030330) for regions of interest in the spine and proximal femur. With the exception of the use of an asynchronous calibration method, the new device has the same technological characteristics as its predicate QCT Pro devices that calibrate bone mineral density with reference to a CT calibration phantom scanned simultaneously with a patient. BMD estimates derived with the asynchronous calibration method are suitable for comparison to the same reference data sets as are used with the QCT Pro predicate devices. Such reference data comparisons provide an aid to the physician in identifying patients with abnormally high or low bone mineral density.

Device Characteristic	**CliniQCT** **Installed and Used in Conjunction with QCT Pro**	**QCT Pro** **(K894854, K002113, K030330)**
Device provides estimates of bone mineral content (BMC).	✓	✓
Device provides estimates of bone mineral density (BMD).	✓	✓
BMC and BMD estimates are provided for the spine and hip.	✓	✓
BMC and BMD estimates are derived using the principals of Quantitative Computed Tomography (QCT)	✓	✓
BMC and BMD estimates are provided standardized to an aqueous K_2HPO_4 bone density standard.	✓	✓

BMC and BMD estimates are derived relative to a phantom standard scanned: with the patient separate from the patient, either before or after patient scan	both scan modes accessible with installation of CliniQCT ✓ ✓	 ✓
Precision, (*in vitro*) relative to calibration reference standard.	Non-inferior to QCT Pro	Volume Density: 1.4 mg/cm^3 (0.7% at a nominal volume density of 200 mg/cm^3) Area Density: 0.007 g/cm^2 (0.7% at a nominal area density of 1.0 g/cm^2)
Precision, (*in vivo*) patient.	Non-inferior to QCT Pro	Spine: Up to 1% Total Hip ROI: 0.011 g/cm^2 (1.1% at 1.0 g/cm^2) Femoral Neck: 0.012 g/cm^2 (1.2% at 1.0 g/cm^2)
Accuracy, relative to calibration reference standard	Unbiased	Unbiased
Radiation dose associated with examination is within currently accepted guidelines regarding radiation health risks associated with common radiologic diagnostic procedures. *Note, QCT Pro does not directly control the delivery of radiation to a patient, but rather makes use of images acquired from medical CT scanners approved for diagnostic, medical x-ray, CT imaging purposes.* Device can be used to provide retrospective measurements from CT scans acquired for other purposes without exposing the patient to additional ionizing radiation beyond that required for the other purposes. Device can be used to provide BMD and BMC measurements from CT scans acquired for multiple purposes (e.g., dual use of images acquired for CT colonography and bone density screening) without exposing the patient to additional ionizing radiation beyond that required for the other, non-QCT, purpose(s).	✓ ✓ ✓	✓ ✓

Device Testing

The design and performance of CliniQCT installed with QCT Pro was evaluated and compared to QCT Pro using retrospective data analysis, phantom testing and prospective patient studies. Software validation was performed using standard techniques.

Summary

Based on the similarities in analytical methods, calibration standards and performance testing, it is concluded that CliniQCT used in conjunction with QCT Pro is substantially equivalent to predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act. No new safety or effectiveness issues are raised by CliniQCT.

Signature

J. Keenan Brown, PhD
Director of Research and Development
Mindways Software, Inc.